1.4 510(K) Summary

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number _____ **Date Prepared: May 13,2003**

Submitter	Contact Person
Beckman Coulter, Inc 1000 Lake Hazeltine Drive Chaska, MN 55318	Lynn Weist Staff Regulatory Affairs Specialist Phone: 952-368-1271 Fax: 952-368-7710

General Information

Proprietary Name	Access® Immunoassay System Toxo IgM II Assay
Classification Name	Toxoplasma gondii serological reagents
Device Class	Class II
Legally Marketed (Unmodified) Device	Access Toxo IgM II Reagents for use on the Access Immunoassay System (K003259, cleared 6/13/01)

Device Description

The Access Toxo IgM II reagents consist of reagent packs, controls, QC, substrate and wash buffer.

Intended Use

The Access Toxo IgM II assay is a paramagnetic-particle, chemiluminescent immunoassay for the qualitative determination of *Toxoplasma gondii*-specific IgM antibody in adult human serum and plasma, using the Access Immunoassay Systems. The Access Toxo IgM II assay is presumptive for the diagnosis of acute, recent or reactivated *Toxoplasma gondii* infections in males and pregnant or non-pregnant females. It is recommended this assay be performed in conjunction with a *Toxoplasma gondii*-specific IgG antibody assay.

510(k) Summary

Description of the Modification to the Legally Marketed Device

The modification to the Access Toxo IgM II reagents is to add a new instrument platform, the Beckman Coulter UniCel™ DxI 800 Access® Immunoassay System, to the family of Access Immunoassay Systems. The DxI System is a new model within the same model series of Access Immunoassay Systems manufactured and distributed by Beckman Coulter, Inc. The DxI System was cleared for marketing by FDA on January 28, 2003, (K023764).

The DxI uses the same Access Toxo IgM II reagents, controls and QC, packaged the same as for the Access 2 System. The formulations of the substrate and wash buffer used with the Access Toxo IgM II assay are unchanged. There are no changes to the intended uses, technical specifications or final performance specifications and claims for the assay.

Supporting Data

In order to demonstrate that the Access Toxo IgM II assay on the DxI System is substantially equivalent to the Access Toxo IgM II assay on the Access 2 System, reproducibility and concordance studies were conducted. The Access Toxo IgM II assay met the established acceptance criteria for reproducibility and concordance. Method comparison (linear regression) using the concordance study data was completed and showed good correlation between the DxI and Access 2 Systems.

Conclusion

The information provided in this submission supports a substantial equivalence determination, and therefore, 510(k) premarket notification clearance of the Access Toxo IgM II Reagents on the UniCel DxI 800 Access Immunoassay System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 2 2003

Ms. Lynn Weist
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Re: k031506
Trade/Device Name: Access® Toxo IgM II Reagents for use on the Access® Immunoassay Systems
Regulation Number: 21 CFR 866.3780
Regulation Name: Toxoplasma Gondii Serological Reagents
Regulatory Class: Class II
Product Code: LGD
Dated: May 13, 2003
Received: May 14, 2003

Dear Ms. Weist:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

1.3 Indications for Use Statement

510(k) Number (if known): K031506

PAGE 1 OF 1

Device Name: Access® Toxo IgM II Reagents for use on the Access® Immunoassay Systems

Indications for Use:

The Access Toxo IgM II assay is a paramagnetic-particle, chemiluminescent immunoassay for the qualitative determination of *Toxoplasma gondii*-specific IgM antibody in adult human serum and plasma, using the Access Immunoassay Systems. The Access Toxo IgM II assay is presumptive for the diagnosis of acute, recent, or reactivated *Toxoplasma gondii* infections in males and pregnant or non-pregnant females. It is recommended this assay be performed in conjunction with a *Toxoplasma gondii*-specific IgG antibody assay.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) OR Over-the-Counter Use_____ (Optional Format 1-2-96)

Freddie M. Poole

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031506